In the U.S. Patent and Trademark Office

Inventor	Hallowitz, Robert ; et al.	Paper:	
Serial number:	09/296,534	Group:	
Filed:	11/8/2001	Examiner:	
Title:	Methods And Compositions For Determining Latent Viral Load		

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Petition to Revive Unintentionally Abandoned Application (37 CFR 1.137)

Applicant has received a Notice of Abandonment, mailed 10/6/2004, of the patent application referenced above.

Applicant hereby petitions to revive the patent application referenced above. The entire delay in filing the required reply from the due date for reply until the filing date of a grantable petition pursuant to 37 CFR 1.137 was unintentional.

Applicant submits herewith a Response to the Nonfinal Office Action mailed 12/17/2003.

Applicant is a small entity. Accordingly, the applicable fee for this petition is $750. Applicant submits herewith a check for $750, in payment of the petition fee.

Respectfully submitted,

V. Gerald Grafe 2/23/05

V. Gerald Grafe — date
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Certificate of Mailing

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited on the date shown below with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Petition; Commissioner for Patents; P.O. Box 1450; Alexandria, VA 22313-1450.

Feb. 23, 2005 — V. Gerald Grafe

date — name

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Response to Office Action

Applicant has reviewed the Office Action mailed 12/17/2003, and submits the following in complete response thereto, and requests reconsideration of the Claims presented.

This Response:

Traverses the rejections under 35 U.S.C. 112;

Adds new claim 23 that avoids the wording questioned by the Office.

Fee

After this Response, there are 21 total claims, of which 4 are independent. Applicant previously paid for 22 total claims, and for 4 independent claims. Accordingly, Applicant believes that no fee is due with this Response.

Respectfully submitted,

V. Gerald Grafe 2/23/05

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In the Claims.

The listing of Claims replaces all previous listings.

Claim 1 (previously presented). A method of determining the latent viral load in a host infected with HIV comprising:

Contacting resting lymphoid mononuclear cells obtained from the host with an effective amount of an agent which activates an HIV virus integrated into the genome of the cells; and

Detecting the expression of cell-surface gp120 on intact cells after the cells have been contacted with the agent and counting the intact cells therein, wherein the number of intact cells expressing cell-surface gp120 is a measure of latent viral load.

Claim 2 (previously presented). The method of Claim 1, comprising, prior to said contacting, obtaining the resting lymphoid mononuclear cells by the steps of:

a) obtaining a sample cell population;

b) depleting the sample cell population of cells expressing cell-surface gp120; and

c) depleting sample cell population of cells expressing HLA-DR, whereby resting lymphoid mononuclear cells are obtained.

Claim 3 (previously presented). The method of Claim 2, wherein the sample cells are depleted of gp120 expressing cells by the steps of:

a) contacting sample cells with gp120-specific antibodies, said antibodies conjugated to a capture moiety, under conditions effective for the antibodies to attach to gp120 on the surface of cells, thereby forming labeled-cells;

b) contacting the labeled-cells with capture moiety-specific antibody under conditions effective for the capture moiety-specific antibody to attach to the labeled-cells, thereby forming a complex-labeled cells; and

c) removing the complex-labeled cells, thereby depleting sample cells of gp120+ cells.

Claim 4 (previously presented). The method of Claim 3, wherein the capture moiety-specific antibody is conjugated to magnetic particles.

Claim 5 (previously presented). The method of Claim 3, wherein the capture moiety is FITC and the capture moiety-specific antibody is FITC-specific antibody conjugated to magnetic particles.

Claim 6 (previously presented). The method of Claim 4, wherein the magnetic particles are 10-100 nm in diameter.

Claim 7 (previously presented). The method of Claim 5, wherein the magnetic particles are 10-100 nm in diameter.

Claim 8 (previously presented). A method of Claim 3, wherein the removing is accomplished by a magnetic field acting on the magnetic particles.

Claim 9 (previously presented). The method of Claim 2, further comprising: separating CD4+ cells from the sample prior to said contacting.

Claim 10 (previously presented). The method of Claim 2, further comprising: separating CD8+ cells from the sample prior to said contacting.

Claim 11 (previously presented). The method of Claim 2, wherein the depleting sample cell population of cells expressing HLA-DR is accomplished by flow cytometry cell sorting and said cells are labeled with a fluorochrome-labeled antibody specific-for HLA-DR.

Claim 12 (previously presented). The method of Claim 1, wherein the resting lymphoid mononuclear cells are obtained from lymphoid tissue.

Claim 13 (previously presented). The method of Claim 1, wherein the agent is phorbol ester or a cytokine.

Claim 14 (cancelled).

Claim 15 (previously presented). The method of Claim 1, wherein the measure of latent viral load is compared to an established cell line harboring latent HIV-1.

Claim 16 (previously presented). The method of Claim 15, wherein the cell line is OM-10.1, U1, or Jurkat cells.

Claim 17 (withdrawn). A method of treating a viral infection comprising measuring the latent viral load in an HIV-infected patient; and determining whether to administer to the patient an agent capable of activating an HIV virus integrated into the genome of a cell by the value of the latent viral load.

Claim 18 (previously presented). A method determining latent viral load in a host infected with HIV comprising,

depleting a cell population obtained from the host of cells expressing cell-surface gp120 to obtain a depleted cell population, the original cell population comprising intact cells susceptible to HIV-infection, and

counting, in said depleted cell population, the number of intact cells expressing cell-surface gp120, wherein said depleted cell population has been contacted with an agent which activates HIV integrated into the genome of said cells under conditions effective for said agent to activate integrated HIV to obtain a determined number of cells,

whereby said latent viral load in the host is the determined number of cells.

Claim 19 (previously presented). A method of determining latent viral load in a host infected with HIV comprising,

Depleting a cell population obtained from the host of cells expressing cell-surface gp120 to obtain a depleted cell population, the original cell population comprising intact cells susceptible to HIV-infection,

Contacting said depleted cell population with an agent which activates HIV integrated into the genome of said cells under conditions effective for said agent to activate integrated HIV,

Counting, in said depleted cell population, the number of intact cells expressing cell-surface gp120 to obtain a determined number of cells,

Whereby said latent viral load in the host is the determined number of cells.

Claim 20 (previously presented). The method of Claim 1, wherein the step of detecting the expression of cell-surface gp120 further comprises isolating the intact cells.

Claim 21 (previously presented). The method of Claim 1, wherein the detecting the expression of cell-surface gp120 pr the counting of intact cells is performed using flow cytometry or fluorescent microscopy.

Claim 22 (previously presented). The method of Claim 20, wherein the detecting the expression of cell-surface gp120 or counting of intact cells is performed using flow cytometry or fluorescent microscopy.

Claim 23 (new). A method of determining an indication of the latent viral load in a host infected with HIV comprising:

Contacting resting lymphoid mononuclear cells obtained from the host with an effective amount of an agent which activates an HIV virus integrated into the genome of the cells; and

Detecting the expression of cell-surface gp120 on intact cells after the cells have been contacted with the agent and determining a measure related to the intact cells therein, wherein the measure is an indication of the latent viral load.

Remarks

Status of the Application

The Office rejected Claims 1, 18, and 19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which application regards as the invention.

The Office rejected Claims 1-13, 15-16, and 18-22 under 35 U.S.C. 112, first paragraph, as not enabled by the disclosure.

The Office withdrew all rejections based on prior art.

Rejections under 35 U.S.C. 112

The Office rejected Claims 1, 18, and 19 under 35 U.S.C. 112 as indefinite, asserting that it was unclear how the number of cells determined in the claim steps was correlated to the viral load in a host. The Office asserted that there was no language serving to correlate the result from the recited steps with the preamble. The Office rejected Claims 1-13, 15-16, and 18-22 under 35 U.S.C. 112, first paragraph, as not enabled by the disclosure, asserting that the specification did not enable one skilled in the art to practice the invention commensurate with the scope of the claims. The Office stated that, "to determine the latent viral load in an individual, one must determine the number of latently infected cells in all cell populations," and that the specification did not enable one skilled in the art to do so. Office Action page 5 lines 19-22.

Applicant respectfully traverses these rejections. The Office defines the invention to require "quantifying all latently infected cells present in an HIV-1 infected host," and then bases the rejection on Applicant's purported failure to enable or claim an invention meeting the Office's definition. Office Action page 5 lines 9-10. The Office's definition and requirement, however, are not consistent with Applicant's specification and claims.

It is a fundamental principle contained in 35 U.S.C. 112, second paragraph that applicants are their own lexicographers. MPEP 2173.01. Applicants can define in the claims what they regard as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification. MPEP § 2111.01. In the present application, Applicant defines the term "latent viral load" to correspond to the scope of the steps in the claims; the Office's rejection is founded on an improper redefinition of the term to require an exhaustive, perfect measurement of all possible latently infected cells. Applicant's specification, however, defines the term to be a new measure of HIV status, one that gives useful information relative to latent viral load; the term does not require a comprehensive count of every cell. As the Office points out, many types of cells can be latently infected. Applicant teaches, and claims, methods of measuring at least some of such cells, thereby providing information about latent infection. The steps in the claims accomplish this measurement, and Applicant submits that they are consistent with the definition of the term in the specification. Some example passages from the specification (emphasis added):

Page 1, lines 28-30. The HIV-1 stable latency quantitation system as described below provides a means to establish **a measure of a new HIV status** within a patient. We call this measure the "latent viral load."

Page 2, lines 1-5. The present invention relates to ... for detecting, measuring, and/or quantifying stable viral latency as **a new measure of viral status** in a host infected with a virus which has integrated into the host genome.

Page 2, lines 11-15. The present invention provides means to establish a measure of a new viral status of a virally-infected host by identifying the presence and/or amount of cells in such host which are latently infected. **This new status is referred to as "latent viral load"** since it is a measure of the presence of dormant virus in an infected host.

Page 2, lines 25-27. To measure the "latent viral load," in accordance with a preferred embodiment of the present invention, a population of sample cells is obtained from a desired source, such as an infected patient.

Page 3, lines 9-12. The corresponding latent viral load can be quantified in any useful way, including, by counting the cells which express the viral cell-surface (e.g., as cell number per unit volume), measuring the amount of agent which produces the infection, or any other useful way of expressing it.

The term "latent viral load" accordingly does not require the comprehensive measurement that the Office has imposed. A count of even some latently infected cells provides useful information about latent infection, and the claim steps provide such a count.

Applicant submits that the subject Claims are commensurate with the enabling teaching in the specification, and that the subject Claims, read in light of the definitions in the specification, are definite.

New Claim 23

Applicant has introduced new Claim 23, based on Claim 1 except that the "determination of the latent viral load" in the preamble has been changed to a "determination of an indication of the latent viral load." Applicant submits that new Claim 23 is allowable over the art for similar reasons as Claim 1, and that the revised wording of new Claim 23 obviates the rejections under 35 U.S.C. 112 applied to Claim 1.